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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,167	09/23/2003	Andrew Bradbury	021362-000300US	2827

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/670,167	Applicant(s) BRADBURY ET AL.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
 4a) Of the above claim(s) 6, 7 and 18-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 8-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/17/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of Claims

1. Response to restriction requirement filed 10/17/05 is acknowledged. Applicant elected, with traverse, Group I, claims 1-17. Applicant argues that Groups I and II are in the same classification. However, despite being generally classified in the same classification, a reference teaching a bifunctional polypeptide of Group I will not teach or suggest a multifunctional polypeptide of Group II which has different structure (i.e., it has a polymerized second member of coiled coil, the feature absent in the product of group I). With respect to method of claim 56, the product of Group I can be used for methods other than the method of claim 56. With respect to method of claim 57, the method does not utilize the product of claim 1. The restriction requirement is still deemed proper and is therefore made FINAL. Claims 18-59 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected groups.

As per election of species requirement, applicant elected antibodies as binding partner, and fluorescent label as reporter group. Claims reading on the elected species are 1-5,8-11. Claims 6,7 are withdrawn from consideration as directed to non-elected species.

Sequence Listing

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1)

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and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c). A copy of the "Sequence Listing" in computer readable form has not been received as required by 37 C.F.R. 1.821(e).

Applicant must provide: 1. An initial computer readable form (CRF) copy of the "Sequence Listing"; 2. An initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification. 3. A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

Failure to provide the above information will be non-responsive.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. The claim recites "A coil" and "B coil". Although specification presents representative examples (paragraph [0081]) the terms "A coil" and "B coil" are not defined in the specification, and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 1,4-11 are rejected under 35 U.S.C. 102(e) as anticipated by Craig et al (US 20020197606; filing date 01/25/2001)

The instant claims are drawn to bifunctional polypeptide comprising a binding ligand linked to a first member of a coil-coil binding pair and a reporter molecule linked

to the second member of a coil-coil binding pair, wherein binding between the first coil domain and the second coil domain joins the binding ligand to the reporter molecule.

Per election of species, the bifunctional polypeptide comprises an antibody linked to a first member of a coil-coil binding pair and a fluorescent dye as a reporter molecule linked to the second member of a coil-coil binding pair.

Craig et al teach bifunctional polypeptide comprising a "binding partner polypeptide" linked to a first member of a coil-coil binding pair and a reporter molecule linked to the second member of a coil-coil binding pair. See, for example Fig 1. Coiled coil pair can be used as a "tag" connecting a "binding partner polypeptide" and a reporter molecule wherein binding between the first coil domain and the second coil domain joins the binding ligand to the reporter molecule. See the following section of the reference:

[0180] Both heterodimeric and homodimeric coiled-coil polypeptides can be used as tags for isolated binding partner polypeptides. A first part of a heterodimer or homodimer coiled-coil polypeptide (the tag) is attached to a binding partner as, for example, a fusion protein, or by covalent or non-covalent attachment. Thus, the first part of the heterodimer or homodimer can be specifically and predictably placed in a binding partner polypeptide. A second part of the heterodimer or homodimer coiled-coil polypeptide (the detector molecule) can be, for example, chemically synthesised or produced recombinantly and labeled with one or more reporter molecules, for example, an antigen, an antibody, a single chain antibody, biotin, radioactive amino acids, a reporter enzyme, a chemical fluorophore, or a fluorescent protein. The first part of the heterodimer or homodimer carrying the unlabeled coil partner attached to the binding partner is mixed with the tagged second part of the homodimer or heterodimer in conditions allowing coiled-coil formation. The formation of a coiled-coil dimer will stably attach the tag to the binding partner polypeptide.

[0181] The use of a tag, such as a coiled-coiled, allows for a specific and controllable method of labeling binding partner polypeptide domains at predictable locations. The ability to provide a tag at a predictable location on a binding partner polypeptide is very advantageous. For example, a chemical fluorophore can be coupled to various positions on a coiled-coil heterodimer or homodimer for optimal effect in subsequent fluorescent assays. The length of a linker between the coil and a binding partner polypeptide can also be varied to position the fluorescent molecule at different distances from the protein and also to allow more or less flexibility and movement between the binding partner and the fluorescent molecule.

With respect to claim 4, the amount of repeats is 3 or greater. See paragraph [0177].

As described above, a reporter molecule can be a fluorescent label or fluorescent protein. For more details on selection of such reporter molecules see pages 19-22.

With respect to the "binding ligand" in the instant claims, the "binding partner polypeptide" linked to a first member of a coil-coil binding pair in the reference reads on the "binding ligand" as instantly claimed in general. More specifically, with respect to the use of antibodies in instantly claimed "bifunctional polypeptide", the reference teaches various uses of antibodies. For example, an antibody can be a part of a detector molecule and be associated, e.g., via a covalent bond to a tagged binding partner, thus making it a part of the first part of the tagged complex. See paragraph [0184]. Said paragraph further provides a broad list of antibodies and their fragments that can be used. See also, paragraphs [0270]-[0275].

It is the Examiners position that all the elements of Applicant's invention with respect to the specified claims are instantly disclosed by the teaching of the reference cited above.

5. Claims 2,3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (US Patent 6,787,368) or Segal et al (US Patent 6,300,141) as applied to claims 1,4-11 above, and further in view of Wong et al (US Patent 6,787,368) or Segal et al (US Patent 6,300,141).

With respect to claims 2,3 addressing particular coil pairs, coils E,K, A,B, are addressed as leucine zippers (see specification, paragraph [0081]). Craig et al teach

that any pair of interacting coiled coils, such as leucine zippers in particular, can be selected as tags to form a coiled-coil pair. See pages 17-18, paragraphs [0176]-[0181]. The reference does not specifically teach the use of K-coils or E-coils, i.e., coil subunits which are referred to as K-coils, referring to positively charged subunits whose charge is provided predominantly by lysine residues, and E-coils, referring to negatively subunits whose charge is provided dominantly by glutamic acid residues. However, as the use of such coils as subunits in coiled-coil pairs is well known – see US 6787368, col. 12, lines 12-21, col. 16, lines 61-65, or US 6300141, col. 25, lines 34-37, col. 30, lines 15-35 - use of them as tags in bifunctional conjugates of Craig et al would be a *prima facie* obvious selection for an artisan as a part of a routine optimization. The same applies for a pair of complementary A- and B- leucine zippers.

Conclusion.

6. No claims are allowed
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb
12/18/2005